UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BROOKE WARREN, individually and as EXECUTOR of the ESTATE OF PHILIP T. WARREN, deceased,

Plaintiff,

v.

RESMED CORP. and APRIA HEALTHCARE LLC, a subsidiary of APRIA HEALTHCARE GROUP, INC.,

Defendants.

CASE No. 1:21-cv-08531

Hon. John F. Keenan, U.S.D.J. Hon. Kevin N. Fox, U.S.M.J.

AMENDED COMPLAINT

The Plaintiff, by her attorneys Silver & Kelmachter, LLP, as and for her Amended Complaint against the Defendants, does allege as follows upon information and belief:

- 1. That at all times hereinafter mentioned, the plaintiff was a resident of the State of New York and the County of New York.
- 2. That at the time of his death on July 25, 2020, the decedent Philip T. Warren was a resident of the State of New York, County of New York.
- 3. That on February 18, 2021, the Plaintiff was appointed by the New York County Surrogate to be the Executor of the Estate of the decedent Philip T. Warren.
- 4. That at all times hereinafter mentioned, the defendant ResMed Corp. was and still is a foreign corporation, duly organized and existing under the laws of the State of Delaware.
- 5. That at all times hereinafter mentioned, the Defendant ResMed Corp., was a foreign corporation which was duly authorized by the Secretary of State of the State of New York to conduct business within the State of New York.

- 6. That prior to and at the time of the events described herein, the Defendant ResMed Corp., was engaged in interstate commerce and did derive a substantial portion of its revenue from interstate commerce, including interstate commerce involving customers and/or distributors in the State of New York.
- 7. That prior to and at the time of the events described herein, the Defendant ResMed Corp., did avail itself of a significant marketplace within the State of New York and did market its goods and services within the State of New York and, as part of its business operations and on an ongoing basis, did provide service and support for multiple customers and distributors which bought, rented and used its products within the State of New York which used its products within the State of New York.
- 8. That at all times hereinafter mentioned, the Defendant ResMed Corp., knew or reasonably should have known that its tortious acts and omissions in connection with its manufacturing and product support operations outside of the State of New York would have consequences within the State of New York.
- 9. That the Defendant ResMed Corp., is subject to the jurisdiction of the Supreme Court of the State of New York as a consequence of its ongoing interstate business operations which included regular commercial activities within the State of New York, either by its own employees and/or by its agents and distributors, and in placing its products into the stream of commerce outside of the State of New York and in committing negligent acts and omissions outside of the State of New York which would foreseeably have injurious consequences within the State of New York.
- 10. That at all times hereinafter mentioned, the Defendant ResMed Corp., did regularly do business and solicit business in the State of New York.

- 11. That at all times hereinafter mentioned, the Defendant ResMed Corp., received substantial revenue from goods used or consumed, and/or its associated services rendered, in the State of New York.
- 12. That at all times hereinafter mentioned, the Defendant ResMed Corp., manufactured, marketed, produced, sold and distributed a certain product called the "Astral 150 Ventilator."
- 13. That at all times hereinafter mentioned, the Defendant ResMed Corp., was in the business of designing, developing, manufacturing, assembling, producing, testing, inspecting, advertising, selling and distributing the Astral 150 Ventilator and other products for the purpose of sale and use to the general public, within the State of New York and elsewhere.
- 14. That at all times hereinafter mentioned, the Defendant ResMed Corp., was in the business of manufacturing, selling and distributing the Astral 150 Ventilator for the purpose of its sale and use to businesses.
- 15. That at all times hereinafter mentioned, and prior to July 25, 2020, the Defendant ResMed Corp., manufactured, sold, distributed and delivered to various retailers and distributors the above-mentioned product.
- 16. That the Defendant ResMed Corp., placed the aforesaid product known as the Astral 150 Ventilator into the stream of interstate commerce for sale and use to the general public, including plaintiff's decedent Philip T. Warren.
- 17. That before July 25, 2020, Defendant ResMed Corp., for good and valuable consideration, sold, leased, rented, serviced, repaired, and delivered the subject ventilator to plaintiff's decedent, Philip T. Warren.

- 18. That on July 25, 2020, Plaintiff's decedent Philip T. Warren used said product of Defendant ResMed Corp., for the purposes intended.
- 19. That at all times hereinafter mentioned, the Defendant APRIA HEALTHCARE GROUP, INC., was and still is a foreign corporation, duly organized and existing under the laws of the State of Delaware.
- 20. That at all times hereinafter mentioned, the Defendant APRIA HEALTHCARE GROUP, INC., was a foreign corporation which was duly authorized by the Secretary of State of the State of New York to conduct business within the State of New York.
- 21. That at all times hereinafter mentioned, the Defendant APRIA HEALTHCARE LLC was and still is a foreign limited liability company, duly organized and existing under the laws of the State of Delaware.
- 22. That at all times hereinafter mentioned, the Defendant APRIA HEALTHCARE LLC was a foreign limited liability company which was duly authorized by the Secretary of State of the State of New York to conduct business within the State of New York.
- 23. That at all times hereinafter mentioned, the Defendant APRIA HEALTHCARE LLC was a domestic limited liability company which was duly organized and existing under the laws of the State of New York.
- 24. That at all times hereinafter mentioned, the defendant Apria Healthcare LLC was a wholly-owned subsidiary of the defendant Apria Healthcare Group, Inc.
- 25. That prior to and at the time of the events described herein, the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC (the "Apria Defendants") was/were engaged in interstate commerce and did derive a substantial portion of

its/their revenue from interstate commerce, including interstate commerce involving customers within the State of New York.

- 26. That prior to and at the time of the events described herein, the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC did avail themselves of a significant marketplace within the State of New York and did market its/their goods and services within the State of New York and, as part of its business operations, did provide service and support for multiple customers within the State of New York which used its products and services within the State of New York, on an ongoing basis.
- 27. That at all times hereinafter mentioned, the duly authorized officers and employees of the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC knew or reasonably should have known that tortious acts and omissions in connection with its marketing and product support operations for manufactured goods outside of the State of New York, would have injurious consequences within the State of New York.
- 28. That the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, is/are subject to the jurisdiction of the Supreme Court of the State of New York as a consequence of its/their ongoing business operations which included regular commercial activities within the State of New York, either by its own employees and/or by its agents and distributors, and in placing its products into the stream of commerce outside of the State of New York, in committing negligent acts and omissions outside of the State of New York which would foreseeably have injurious consequences within the State of New York, and by its business activities within the State of New York including the maintenance of a business office within the State of New York at 21-57 Borden Avenue in Long Island City, NY 11101.

- 29. That at all times hereinafter mentioned, the duly authorized officers or employees of the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, committed tortious acts or omissions within the State of New York.
- 30. That at all times hereinafter mentioned, the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, regularly did business and solicited business in the State of New York.
- 31. That at all times hereinafter mentioned, the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, received substantial revenue from goods used or consumed, or services rendered, in the State of New York.
- 32. That at all times hereinafter mentioned, the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, manufactured, produced, marketed, sold and distributed a certain product called the "Astral 150 Ventilator."
- 33. That at all times hereinafter mentioned, the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, were in the business of selling, manufacturing, leasing, renting, servicing, repairing, and distributing Astral 150 Ventilators for the purpose of sale and use to customers and individuals within the State of New York and elsewhere.
- 34. That the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, provided the aforesaid product called Astral 150 Ventilator to the general public, including plaintiff's decedent.
- 35. That on or before July 25, 2020, Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, by their duly authorized officers and employees and in the regular course of their business, and following the receipt of the subject ventilator,

inspected, examined, tested, serviced, maintained, prepared, and otherwise worked upon the said ventilator.

- 36. That before July 25, 2020, Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, for good and valuable consideration, sold, rented, leased, serviced, repaired, maintained, and delivered the subject ventilator to plaintiff's decedent, Philip T. Warren.
- 37. That on July 25, 2020, Plaintiff's decedent Philip Warren used said product of Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC, for its intended purpose.
- 38. That at all times hereinafter mentioned, Plaintiff's decedent Philip T. Warren rented or leased a certain Astral 150 Ventilator from the Defendants APRIA HEALTHCARE GROUP, INC., and APRIA HEALTHCARE LLC.
- 39. Plaintiff's decedent Philip T. Warren had Charcot-Marie-Tooth Type 1A disease ("CMT 1A"), a neurological disorder affecting peripheral nerves, and specifically, Plaintiff's decedent's phrenic nerve, which causes the diaphragm to contract and relax and helps control breathing.
- 40. Plaintiff's decedent Philip T. Warren's condition of CMT 1A required the support of a ventilator to assist his breathing as he was unable to expel carbon dioxide on his own.
- 41. Prior to July 25, 2020, Plaintiff's decedent Philip T. Warren was prescribed an Astral 150 Ventilator by his physician pulmonologist, Dr. David Berlin, to provide non-invasive positive pressure ventilation, oxygen, and carbon dioxide removal through a face mask connected to the ventilator to be used during sleep and intermittently throughout the day.

- 42. Plaintiff's decedent Philip T. Warren rented and utilized the Astral 150 Ventilator (Serial Number: 22171023130) which provided mechanical ventilation, non-invasive ventilation assistance, and/or non-invasive positive pressure ventilation by delivering oxygen, pressure, and volume ventilation through a valve, leak circuit, and/or facemask during sleep and intermittently throughout the day.
- 43. The Astral 150 Ventilator utilized by Plaintiff's decedent Philip T. Warren on July 25, 2020 was designed, manufactured, marketed, and distributed by Defendant ResMed Corp. and also distributed and sold to Plaintiff's decedent Philip T. Warren by the Apria Defendants.
- 44. Plaintiff's decedent Philip T. Warren regularly required ventilation support from the Astral 150 Ventilator due to his condition of CMT 1A. That on July 25, 2020, Plaintiff's decedent Philip T. Warren used the subject ventilator for its intended purpose and in a reasonably foreseeable manner.
- 45. That on July 25, 2020, plaintiff's decedent was found to be unresponsive while using the subject ventilator.
- 46. That on July 25, 2020, Plaintiff Brooke Warren observed a gap or opening between the face mask of the subject ventilator and Plaintiff's decedent Philip T. Warren's face which impaired the functioning of the subject ventilator in a manner which should have caused an alarm to sound but did not. As a result, Plaintiff's decedent Philip T. Warren was caused to sustain anoxia resulting in his death on July 25, 2020.
- 47. That on July 25, 2020, Plaintiff Brooke Warren did not hear or observe any alarms sounding from the subject ventilator when she found Plaintiff's decedent Philip T. Warren unresponsive.

- 48. The Astral 150 Ventilator is allegedly designed and manufactured in such a way as to activate an audible and visual alarm to alert the user or caretaker to a condition that requires attention to ensure user safety such as power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection.
- 49. That had the Astral 150 Ventilator activated an audible and visual alarm to alert Plaintiff's decedent or his wife, who was home at the time, to a condition that required attention including but not limited to power failure, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection, as allegedly designed and manufactured to do, then Plaintiff's decedent could have been alerted to the issue and have avoided this catastrophic occurrence.
- 50. That Defendant ResMed and the Apria Defendants by its/their duly authorized officers, staff, and employees, or through their authorized dealers and agents, warranted and represented, expressly and impliedly, that the subject Astral 150 Ventilator was fit, reasonably safe, and capable of alerting the user to any power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST THE DEFENDANT RESMED CORP., ON BEHALF OF THE ESTATE OF PHILIP T. WARREN BASED UPON NEGLIGENCE, THE PLAINTIFF ALLEGES AS FOLLOWS:

- 51. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "50" with the same force and effect as though same were more fully set forth at length herein.
- 52. That the Defendant ResMed Corp. had a duty to plaintiff's decedent and other customers to use due care in designing, planning, assembling, equipping, testing, inspecting, manufacturing, distributing, calibrating, updating, marketing and selling, warning, instructing and otherwise exercising reasonable care with respect to the Astral 150 Ventilator, which product was placed into the stream of commerce and sold and/or rented either directly or indirectly to plaintiff's decedent.
- 53. The Defendant ResMed Corp., by its/their duly authorized officers, staff, agents and employees breached its/their duty by negligently and carelessly designing, planning, manufacturing, assembling, equipping, testing, inspecting, distributing, marketing and selling, warning, instructing and in otherwise failing to exercise reasonable care relative to the Astral 150 Ventilator so as to cause it to be defective and unreasonably dangerous to any person or persons using it in a reasonably foreseeable manner and for the purpose for which it was intended.
- 54. That the defendant ResMed Corp. manufactured, distributed, leased, rented, and sold a medical device which was unreasonably dangerous and defective in its normal anticipated use. In addition, the defendant ResMed Corp. by its duly authorized officers, agents or employees, had prior notice or knowledge of the unreasonably dangerous conditions which were present in the subject product and failed to take proper and indicated steps to correct or eliminate the defects or unreasonably dangerous conditions, or to sufficiently warn of this.

- 55. That the Defendant ResMed Corp., by its duly authorized officers, agents or employees, was aware of problems and defects pertaining to the alarm system, as well as other systems, functions and mechanisms within the Astral 150 Ventilator product, all of which were components of this product, and failed to correct the problems, such that the product was not reasonably safe in normal use.
- 56. The Astral 150 Ventilator was in an unreasonably dangerous condition at the time it left the control of Defendant ResMed Corp., and it was placed into the stream of commerce for use by customers.
- 57. That the Astral 150 Ventilator, including its related systems and components, failed to provide reasonable warning, alerts, instructions, and other protections and safeguards for the user of the ventilator and failed to afford reasonable protection and safety for its customers while using the product in a foreseeable manner for the purposes intended, which defects were known to the defendant and which it failed to timely correct.
- 58. That the Defendant ResMed Corp., by its duly authorized officers, staff, agents or employees, failed to warn of the defects and unreasonable dangers of the Astral 150 Ventilator and failed to warn its customers of such defects and unreasonable dangers, including the Plaintiff's decedent, Philip T. Warren.
- 59. That the Defendant ResMed Corp., by its duly authorized officers, staff, agents or employees, was negligent in failing to include this product model in a prior recall of medical equipment which it manufactured and distributed which had similar defects and which also needed to be corrected but was not.
- 60. That as a direct and proximate result of the foregoing acts and omissions constituting the negligence of the Defendant ResMed Corp., by its duly authorized officers,

staff, agents or employees, on July 25, 2020, while he was using the Astral 150 Ventilator, the plaintiff's decedent, Philip T. Warren, suffered catastrophic injuries, conscious pain and suffering, mental anguish, and fear of impending death, and the Plaintiff claims all manner of recovery which is available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).

61. Plaintiff demands that a judgment be entered against the Defendant ResMed Corp., in an amount that exceeds the jurisdictional limitations of all lower Courts which would otherwise have jurisdiction herein.

AS AND FOR A SECOND CAUSE OF ACTION BASED UPON STRICT PRODUCTS LIABILITY AGAINST THE DEFENDANT RESMED CORP. ON BEHALF OF THE ESTATE OF PHILIP T. WARREN THE PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 62. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "61" with the same force and effect as though same were more fully set forth at length herein.
- 63. At all times relevant to this action, Defendant ResMed and the Apria Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the Astral 150 Ventilator and the components/accessories used with the ventilator, which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous, or untoward adverse side effects.
- 64. At all times relevant to this action, Defendants knew or reasonably should have known that the Astral 150 Ventilator as designed was unreasonably dangerous, defective, and posed a substantial likelihood of harm when used as directed, including but not limited to the following particulars:

- a. The internal battery was malfunctioning and had to be replaced since the risk of death in ventilator-dependent patients upon such failure was so high when it was feasible to design the Astral 150 Ventilator with an emergency backup battery to prevent insufficient ventilation;
- b. The internal battery malfunction would cause multiple electronic disruptions in function and service of the Astral 150 Ventilator which negatively impacted the efficacy of the flow sensor, oxygen sensor, pressure sensor, and/or alarm system when it was feasible to design, assess, and designate the internal battery problem of the Astral 150 Ventilator as a high-level alarm instead of designating it as a low-level alarm;
- c. The internal battery of the Astral 150 ventilator had inadequate capacity which caused alarm failure due to insufficient electricity in the system when it was feasible to design the Astral 150 Ventilator with an emergency backup battery to prevent insufficient ventilation or to design it with sufficient battery capacity to safeguard against alarm failures due to insufficient electricity in the system so as to prevent false alarms, inaccurate alarms, false positive alarms, false negative alarms, and software problems;
- d. The battery malfunction caused false alarms, inaccurate alarms, false positive alarms, false negative alarms, and/or software problems when it was feasible to design the Astral 150 Ventilator with an emergency backup battery to prevent insufficient ventilation;
- e. The super capacitor would leak and damage the ventilator's electronic system and cause ventilator malfunction when it was feasible to design the Astral 150 Ventilator with an alarm system to alert the user to leakage from the super capacitor;
- f. The humidifier connected to the briefing loop permitted condensation on the oxygen flow sensor, pressure sensor, and/or oxygen saturation sensor which would cause false or inaccurate sensor readings and result in insufficient ventilation when it was feasible to design the Astral 150 Ventilator to alarm or alert the user to excess humidity/moisture;
- g. Failing to configure the alarm threshold properly so as to alert the user to any power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, wrong or low oxygen levels, and/or power disconnections when it was feasible to configure or set the alarm threshold of the Astral 150 Ventilator at an appropriate and/or increased sensitivity to detect such issues; and
- h. Designing and configurating the ventilator to keep operating notwithstanding a leak between the ventilator and the user without alarming when it was feasible to design the Astral 150 Ventilator and configure the sensors' sensitivity to alarm or alert the user to leaks in oxygen/air flow/pressure.
- 65. The design defects alleged above were a substantial contributing cause of the injuries and death suffered by Plaintiff's decedent and the damages sustained by Plaintiff. The

injuries, damages, and death suffered by Plaintiffs were the reasonably foreseeable result of Defendant ResMed and the Apria Defendants' negligence.

- 66. The Astral 150 Ventilator was defectively designed as a reasonable person who knew or should have known of the product's potential for causing injury and of the feasible alternative design(s) would have concluded that the ventilator should not have been marketed in that condition. That the plaintiff could not and would not have discovered the defect through the exercise of ordinary care.
- 67. Had Defendant ResMed and the Apria Defendants performed those tests and studies necessary to determine that the Astral 150 Ventilator and the component parts listed above should not be used on ventilator-dependent patients before Plaintiff's decedent Philip T. Warren's physician prescribed it to him, Mr. Warren would not have suffered the injuries, damages, and death described with particularity above.
- 68. As a direct and proximate cause of Defendant ResMed and the Apria Defendants' negligence, Plaintiff suffered injuries, damages, and death and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- 69. At all times relevant to this action, Defendants ResMed and the Apria Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the Astral 150 Ventilator and the accessories used with the ventilator, which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous, or untoward adverse side effects.

- 70. At all times relevant to this action, Defendant ResMed and the Apria Defendants knew or reasonably should have known that the Astral 150 Ventilator was manufactured in an unreasonably dangerous and defective fashion, and due to a mishap in the manufacturing process, improper workmanship, and/or defective materials, the ventilator posed a substantial likelihood of harm when used as directed for its intended purpose and in a reasonably foreseeable manner, including but not limited to the following particulars:
 - a. The software of the subject ventilator was not properly calibrated, programmed, and/or set to an appropriate threshold during the manufacturing process and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which permitted low flow rate, low pressure, and/or leakage from the ventilator to occur without alerting Mr. Warren to the problem;
 - b. The pressure sensor, flow rate sensor, and/or oxygen saturation sensor of the subject ventilator was not properly calibrated, programmed, and/or set to an appropriate threshold during the manufacturing process and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which permitted low flow rate, low pressure, and/or leakage of oxygen/air from the ventilator to occur without alerting Mr. Warren to the problem;
 - c. The supercapacitor of the subject ventilator was defective and/or not properly connected, positioned, or installed during the manufacturing process and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which permitted leakage of fluid that damaged the electronics and sensors which caused malfunction;
 - d. The internal battery of the subject ventilator had insufficient capacity due to defective materials being utilized during the manufacturing process and it deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession and failed to alert Mr. Warren to the malfunction and caused false alarms, inaccurate alarms, false positive alarms, false negative alarms, and software problems;
 - e. The internal battery of the subject ventilator was faulty at the time it was installed and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which caused multiple electronic disruptions in function and service;

- 71. The manufacturing defects alleged above were a substantial contributing cause of the injuries and death suffered by Plaintiff's decedent and the damages sustained by Plaintiff. The injuries, damages, and death suffered by Plaintiffs were the reasonably foreseeable result of Defendant ResMed and the Apria Defendants' negligence.
- 72. The Astral 150 Ventilator was defectively manufactured as a reasonable person who knew or should have known of the product's potential for causing injury would have concluded that the ventilator should not have been marketed in that condition.
- 73. Had Defendant ResMed and the Apria Defendants performed those tests and studies necessary to determine that the Astral 150 Ventilator and the component parts listed above should not be used on ventilator-dependent patients before Plaintiff's decedent Philip T. Warren's physician prescribed it to him, Mr. Warren would not have suffered the injuries, damages, and death described with particularity above.
- 74. As a direct and proximate cause of Defendant ResMed and the Apria Defendants' negligence, Plaintiff suffered injuries, damages, and death and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- 75. The subject ventilator was manufactured by Defendant ResMed and rented and distributed by the Apria Defendants undertook the periodic service of the machine and its components.
- 76. On July 25, 2020, Plaintiff's decedent Philip T. Warren properly utilized the subject ventilator in a reasonably foreseeable manner and for its intended purpose.
- 77. On July 25, 2020, Plaintiff's decedent Philip T. Warren powered on the subject ventilator and initiated the ventilation program, correctly fitted the face mask circuit to his face,

and thereafter fell asleep. The use of the machine was to protect Mr. Warren during the periods of time while he was asleep.

- 78. That the Astral 150 Ventilator is allegedly designed and manufactured in such a way as to activate an audible and visual alarm to alert the user or caretaker to a condition that requires attention to ensure user safety such as power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection.
- 79. On July 25, 2020, the subject ventilator did not perform as intended. The subject ventilator failed to alarm or alert Mr. Warren or his wife of the power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection of the subject ventilator.
- 80. On July 25, 2020, due to the negligence of the Defendants as aforesaid, and through no fault of the Plaintiff's decedent Philip T. Warren, he was caused to sustain catastrophic injuries resulting in his death due to hypercapnic respiratory failure secondary to neuromuscular diaphragmatic dysfunction in the setting of CMT 1A on July 25, 2020 as a result of the failure of the subject ventilator to perform as intended.
- 81. At all times relevant to this action, Defendant ResMed and the Apria Defendants had a duty to warn all health care providers and consumers or users of the risks, dangers, and adverse side effects of the Astral 150 Ventilator and the component parts / accessories used with the ventilator.

- 82. Prior to July 25, 2020, Plaintiff's decedent Philip T. Warren was prescribed an Astral 150 Ventilator by his physician pulmonologist, Dr. David Berlin of Weill Cornell Medicine.
- 83. Upon information and belief that prior to prescribing the Astral 150 Ventilator to Plaintiff's decedent Philip T. Warren, Dr. David Berlin was provided with the <u>Astral Series User Guide</u> (Exhibit 2) by Defendant ResMed and <u>The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use</u> (Exhibit 3) by the Apria Defendants. The warnings contained therein were inadequate and failed to instruct, advise, inform, apprise, or warn Dr. Berlin of the potential risks, complications, malfunction, and faultiness associated with the use of the Astral 150 Ventilator, including but not limited to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction.
- 84. Upon information and belief that had Dr. David Berlin received additional, different, and/or accurate instructions and warnings concerning the Astral 150 Ventilator, Dr. Berlin would not have prescribed the subject ventilator to Plaintiff's decedent.
- 85. Based on what Defendant ResMed and the Apria Defendants knew or should have known as described above, these Defendants failed to provide proper and necessary warnings to the medical community, and were otherwise negligent in one or more of the following particulars:
 - a. In failing to instruct or warn the medical community that the safety of the Astral 150 Ventilator was not fit for use in ventilator-dependent patients;
 - b. In failing to disclose to the medical community that the Astral 150 Ventilator may cause serious and permanent injury and could result in death;
 - c. In failing to provide to the medical community adequate instructions for the safe use of the Astral 150 Ventilator;

- d. In failing to instruct or warn the medical community that the Astral 150 Ventilator had internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction;
- e. In failing to instruct, warn, inform, or apprise Dr. David Berlin, plaintiff's decedent's pulmonologist, of the potential risks of the Astral 150 Ventilator, including but not limited to, internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction prior to his prescribing the Astral 150 ventilator to plaintiff's decedent;
- f. In failing to instruct, warn, inform, or apprise Dr. David Berlin, plaintiff's decedent's pulmonologist, through the <u>Astral Series User Guide</u> (Exhibit 2) provided by Defendant ResMed of the potential for malfunction due to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction; and
- g. In failing to instruct, warn, inform, or apprise Dr. David Berlin, plaintiff's decedent's pulmonologist, through <u>The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use</u> (Exhibit 3) provided by the Apria Defendants of the potential for malfunction due to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction.
- h. In failing to update its warnings, in failing to recall its product, and in failing to retrofit its product as a result of experience, complaints, product malfunction, and incidents which required that the defendants make necessary updates, changes, safety modifications, and warnings in order to preserve patient safety.
- 86. Upon information and belief that as a result of Defendant ResMed and the Apria Defendants' failure to apprise Dr. David Berlin of the aforesaid risks, complications, malfunction, and faultiness of the Astral 150 Ventilator, Dr. David Berlin could not reasonably advise, warn, instruct, or inform plaintiff's decedent Philip T. Warren of the risks, dangers, and potential malfunction associated with the use of the Astral 150 Ventilator, which proximately caused plaintiff's decedent's injuries.
- 87. Upon information and belief that a reasonable person or prescribing physician who did in fact know of the subject ventilator's potential for causing injury would have concluded that the product should not have been prescribed to patients in that condition.

- 88. That the Defendant ResMed Corp., had a duty to exercise reasonable care in the design, manufacture, assembly, testing, analysis, inspection, marketing, labeling, servicing, calibrating, updating, leasing and sale of its subject Astral 150 Ventilator product.
- 89. In addition to the product defects which were previously and specifically identified, the Defendant ResMed Corp. was further negligent and culpable under strict products liability on account of its failure to properly design and manufacture the Astral 150 ventilator in that it incorporated unreasonably dangerous conditions and defects in its construction and systems, including its electrical system, its alarm system, its software, its electronics, its pumps, its tubing, its mask, its sensors, its breathing apparatus, and aircontaining equipment, which acted to expose the user to an unreasonable risk of harm and injury. That Defendant ResMed failed to exercise proper care and oversight in the manufacture, design, assembly, inspection, marketing, servicing, maintenance, calibration, updating, lease and sale of its Astral 150 Ventilator such that it placed into the stream of commerce a piece of medical equipment which was unreasonably dangerous and defective in its intended use; this includes the related components, systems, and accessories pertaining to this equipment.
- 90. The Defendant ResMed Corp., by its duly authorized officers, staff, agents and employees was negligent in the design and manufacture of its Astral 150 Ventilator, as well as a failure to provide adequate and reasonable warnings as to its function, which product was placed into the stream of commerce, despite the fact that it was unreasonably dangerous and defective in normal use.
- 91. The Defendants ResMed Corp., by its duly authorized officers, staff, agents and employees failed to give adequate warnings of the dangerous and defective design and/or manufacture of the Astral 150 Ventilator and failed to recall and/or retrofit this equipment,

including failing to properly calibrate the product or to timely update its software, although they knew or reasonably should have known of the unreasonable dangers and defects associated with its use and its alarm system, as well as other systems, functions and mechanisms of the product.

- 92. That the Defendant ResMed Corp., was in privity with the Apria Healthcare Group, Inc. and Apria Healthcare, LLC defendants in the manufacture, distribution, leasing, and sale of the subject Astral 150 Ventilator and they did place this product into the stream of commerce whereupon it came to be used by the plaintiff's decedent, who was a customer of the defendants.
- 93. That on July 25, 2020, the plaintiff's decedent suffered catastrophic injuries which led to his death arising from an incident which occurred as a direct and proximate result of the design and manufacturing defects in the Astral 150 Ventilator along with its components, accessories, and alarm system, and the failure to provide adequate and reasonable warnings, all arising from the negligence of the Defendant ResMed Corp., which is responsible and liable to the Plaintiff under principles of strict products liability.
- 94. That as a direct and proximate result of the negligence and strict products liability of the Defendant ResMed Corp., which incorporated design defects and manufacturing flaws into the Astral 150 Ventilator, as week as a failure to warn, which rendered this product unreasonably dangerous and defective in normal use, the plaintiff's decedent suffered catastrophic injuries, conscious pain and suffering, mental anguish, and fear of impending death, as the result of an incident which occurred on July 25, 2020. As a result of the foregoing, the survivors of the decedent and his Estate have sustained all forms of monetary damages which are recoverable under common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).

95. Plaintiff demands that a judgment be entered against the defendant ResMed Corp., in an amount which exceeds the jurisdictional limitations of all lower Courts which would otherwise have jurisdiction herein.

AS AND FOR A THIRD CAUSE OF ACTION ON BEHALF OF THE ESTATE OF PHILIP T. WARREN ARISING FROM BREACH OF WARRANTY AGAINST THE DEFENDANT RESMED CORP., THE PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 96. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "95" with the same force and effect as though same were more fully set forth at length herein.
- 97. The Defendant ResMed and the Apria Defendants, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, expressly warranted and represented that the Astral 150 Ventilator was fit, was reasonably safe, capable, and was of merchantable quality.
- 98. Upon information and belief that Defendant ResMed issued, provided, authored, wrote, and delivered the <u>Astral Series User Guide</u> (Exhibit 2) and the Apria Defendants issued, provided, authored, wrote, and delivered <u>The Patient/Caregiver Instruction Home Ventilator:</u>

 for Invasive and Non-Invasive Use (Exhibit 3) to the medical community and potential purchasers or renters of the Astral 150 Ventilator, and more particularly, to Plaintiff's decedent and his physician, Dr. David Berlin, who prescribed the subject ventilator to him.
- 99. Upon information and belief that Plaintiff's decedent's physician, Dr. David
 Berlin, received, read, and reviewed the ResMed Astral Series User Guide provided by
 Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for
 Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) and relied on the

material statements, affirmations, promises, and express warranties stated therein prior to prescribing the Astral 150 ventilator to Plaintiff's decedent.

- 100. Upon information and belief that Plaintiff's decedent Philip T. Warren received, read, and reviewed the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) and relied on the material statements, affirmations, promises, and express warranties stated therein prior to renting and using the subject ventilator.
- 101. Upon information and belief that Plaintiff's decedent's physician pulmonologist, Dr. David Berlin, completely read and reviewed the entirety of the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) to become familiar, acquainted, and knowledgeable with the operation, use, and maintenance of the Astral 150 Ventilator prior to recommending, advising, and/or prescribing the Astral 150 Ventilator to Plaintiff's decedent.
- 102. Upon information and belief that Plaintiff's decedent Philip T. Warren completely read and reviewed the entirety of the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) to become familiar, acquainted, and knowledgeable with the operation, use, and maintenance of the Astral 150 Ventilator prior to deciding to rent and utilize the subject ventilator.
- 103. Based on what Defendant ResMed and the Apria Defendants knew or should have known as described above, these Defendants deviated from principles of due care,

deviated from the standard of care, and breached one or more of the following express

warranties:

- a. ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2):
 - i. Pg. 1: "The Astral device provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation."
 - ii. Pg. 38: "An internal battery is included in the Astral device. It ensures a continuous power supply when main power is disrupted and no external battery is connected to the device."
 - iii. Pg. 42: "The Astral device activates alarms to alert you to conditions that require attention to ensure patient safety. When an alarm is activated, the Astral device provides both audible and visual alerts, and displays an alarm message in the Alarm display on the information bar. As soon as the activation condition is met, the Astral device provides both audible and visual alerts without delay."
 - iv. Pg. 44: "High priority alarms: Total power failure; Low Pressure; Obstruction / High Pressure; High Pressure; Apnea; Low MVe (minute ventilation); Low MVi (modified ventilation index); High MVi; High MVe; Low Vte (end-tidal volume); High Vte; Low Vti (Inspiratory Tidal Volume); High Vti; Low Resp rate; High Resp rate; High Leak; Ventilation stopped; Low SpO2 (oxygen saturation); High SpO2; Low FiO2 (fraction of inspired oxygen); High FiO2; NV mask blocked; Ventilation not started. Incorrect adapter; Critically low internal battery; Circuit fault; Incorrect circuit; Unexpected restart; Internal Battery inoperable. Medium priority alarms: High pressure; Low PEEP (Positive End Expiratory Pressure); High PEEP; Low pulse rate; High pulse rate; Device overheating; Pressure line disconnected; Last self-test failed; Flow sensor not calibrated; No SpO2 monitoring; No FiO2 monitoring; Low internal battery. Low priority alarms: Power disconnected; Using internal battery; Battery 1 fault; Battery 2 fault; Power fault/ No charging."
- b. The Patient/Caregiver Instructions Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3):
 - i. Pg. 2: "Once you are transitioned from the hospital to your home, Apria will visit you on a regular basis to provide training reinforcement and routine equipment checks and maintenance."
 - ii. Pg. 7: "It is vitally important that the ventilator be checked regularly to guarantee proper function of the ventilator and to protect against accidental changes that may occur with the controls."
 - iii. Pg. 8: "Some problems may occur during home ventilation. Usually these problems are easily resolved and there is no cause for major alarm."
 - iv. Pg. 8: "In the event of a malfunction, it is important to know if there is a patient issue (e.g., the patient needs suctioning, a bronchodilator treatment, etc.) or if the equipment has malfunctioned."
 - v. Pg. 8: "The ventilator must also be monitored routinely for tidal volume setting, respiratory rate, system pressure and alarm function. Mechanical problems, such as

- punctures or kinks in the tubing, malfunction of the exhalation valve, changes in the respiratory rate, alarm failure, or the patient's condition, can result in insufficient or decreased ventilation to the patient. Routine monitoring of the ventilator and tubing can help identify potential problems before they create difficulties."
- vi. Pg. 8: "The ventilator is equipped with safety alarms. These alarms are sensitive to low and high pressures in the ventilator circuit or airway."
- 104. That Defendant ResMed and the Apria Defendants made the aforesaid material statements which amounted to express warranties.
- 105. That Plaintiff's decedent Philip T. Warren relied on the aforesaid warranties and the material statements contained therein, as well as those provided to his physician pulmonologist who prescribed the Astral 150 Ventilator, and such reliance formed the basis for a contract with Defendant ResMed and the Apria Defendants.
- 106. That Plaintiff's decedent Philip T. Warren relied on the aforesaid material statements and express warranties contained in the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) and the information provided by his prescribing physician based on the statements contained therein and Plaintiff's decedent was induced into purchasing or renting the Astral 150 Ventilator based on the express warranties, including but not limited to, that the subject ventilator would alert the user to malfunction(s) which could endanger the user.
- 107. That Defendant ResMed and the Apria Defendants breached the express warranties outlined above and caused catastrophic injuries to plaintiff's decedent as a result of such breach.
- 108. That Plaintiff's decedent Philip T. Warren relied on the aforesaid warranties to his detriment and as a result, was caused to sustain catastrophic injuries.

109. The Defendant ResMed and the Apria Defendants, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, impliedly warranted and represented that the Astral 150 Ventilator was fit, was reasonably safe to use in every respect, capable, was of merchantable quality, and had been manufactured safely.

110. The Defendant ResMed and the Apria Defendants, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, impliedly warranted and represented that the Astral 150 Ventilator would provide both audible and visual alarms without delay to alert the user to conditions that require attention to ensure patient safety, including but not limited to, alarms that are sensitive to low and high pressures in the ventilator circuit or airway; Total Power Failure; Low Pressure; Obstruction / High Pressure; High Pressure; Apnea; Low MVe (minute ventilation); Low MVi (modified ventilation index); High MVi; High MVe; Low Vte (end-tidal volume); High Vte; Low Vti (Inspiratory Tidal Volume); High Vti; Low Resp rate; High Resp rate; High Leak; Ventilation stopped; Low SpO2 (oxygen saturation); High SpO2; Low FiO2 (fraction of inspired oxygen); High FiO2; NV mask blocked; Ventilation not started; Incorrect adapter; Critically low internal battery; Circuit fault; Incorrect circuit; Unexpected restart; Internal Battery inoperable. Medium priority alarms: High pressure; Low PEEP (Positive End Expiratory Pressure); High PEEP; Low pulse rate; High pulse rate; Device overheating; Pressure line disconnected; Last self-test failed; Flow sensor not calibrated; No SpO2 monitoring; No FiO2 monitoring; Low internal battery. Low priority alarms: Power disconnected; Using internal battery; Battery 1 fault; Battery 2 fault; Power fault/No charging.

- 111. That the Defendant ResMed and the Apria Defendants impliedly warranted said product and its components and accessories was fit for the purpose for which it was intended as outlined in detail above, however, the subject ventilator was not reasonably fit for its intended purpose and was defective.
- 112. That the plaintiff's decedent relied upon the implied warranties of Defendant ResMed and the Apria Defendants.
- 113. That Defendant ResMed and the Apria Defendants breached the aforementioned implied warranties.
- 114. That as a result of the breach of the implied warranties by Defendant ResMed and the Apria Defendants, the plaintiff's decedent was caused to sustain catastrophic injuries, including pain and suffering, mental anguish, fear of impending death, and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- 115. The Defendant ResMed Corp., in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, warranted and represented, expressly and impliedly, that the subject Astral 150 Ventilator was fit, was reasonably safe, capable, and was of merchantable quality.
- and accessories was fit for the purpose for which it was intended, warranted that said product and its components and accessories was reasonably safe to use in every respect and had been manufactured safely and warranted that it was good, safe, and proper to use, warranted that the said product and its components and accessories was of merchantable quality and was safe for

use, and provided certain written instructions in connection with the use of the product and its components and accessories.

- 117. Plaintiff's decedent's Astral 150 Ventilator, including its component parts and accessories, was not of a merchantable quality, nor fit for the purpose for which it was intended and was unreasonably dangerous in normal use.
- 118. That the plaintiff's decedent relied upon the express and implied warranties that accompanied the manufacturing, distribution, maintenance, and sale of the equipment.
- 119. Defendant ResMed Corp., breached the express and implied warranties which accompanied the manufacture, distribution, maintenance, and sale of the Astral 150 Ventilator all to the damage and detriment of the decedent.
- 120. That on July 25, 2020, Plaintiff's decedent, while using the subject product in accordance with its intended use, was caused to suffer and sustain catastrophic bodily injuries, which caused conscious pain and suffering and which led to his death.
- 121. That as a result of breach of warranty of the Defendant ResMed Corp., including express and implied warranties, the plaintiff's decedent was caused to sustain catastrophic injuries, including pain and suffering, mental anguish, fear of impending death, and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- 122. As a result of the foregoing, Plaintiff is entitled to compensatory damages in an amount that exceeds the jurisdictional limitations of all lower Courts which would otherwise have jurisdiction herein.

AS AND FOR A FOURTH CAUSE OF ACTION BASED UPON THE WRONGFUL DEATH OF THE DECEDENT AGAINST DEFENDANT RESMED CORP., THE PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 123. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "122" with the same force and effect as though same were more fully set forth at length herein.
- 124. That as a result of the negligence, strict products liability, failure to warn and breach of warranty by the defendant ResMed Corp., which directly and proximately caused the occurrence of the catastrophic incident of July 25, 2020, the plaintiff's decedent, Philip T. Warren, died as a result of his catastrophic injuries on July 25, 2020.
- 125. That as a result of the death of the decedent, the survivors and Estate of the decedent have and will suffer a loss of support, loss of services, loss of parental guidance, loss of advice, and all manner of wrongful death damages as are recoverable at common law and under EPTL § 5-4.1 and § 5-4.3.
- 126. That as a result of the foregoing, Plaintiff is entitled to compensatory damages and additionally, claims entitlement to prejudgment interest from July 25, 2020, that exceeds the jurisdictional limitations of all lower courts which would otherwise have jurisdiction herein.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST THE DEFENDANTS APRIA HEALTHCARE GROUP, INC., AND APRIA HEALTHCARE LLC, ON BEHALF OF THE ESTATE OF PHILIP T. WARREN BASED UPON NEGLIGENCE, THE PLAINTIFF ALLEGES AS FOLLOWS:

- 127. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "126" with the same force and effect as though same were more fully set forth at length herein.
- 128. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, had a duty to plaintiff's decedent and other customers to use due care in designing, planning, assembling, equipping, testing, inspecting, manufacturing, calibrating, updating, distributing,

marketing and selling, warning, instructing and otherwise exercising reasonable care with respect to the Astral 150 Ventilator, which product was placed into the stream of commerce by or through these defendants and was sold, leased and/or rented either directly or indirectly to plaintiff's decedent.

- 129. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by its/their duly authorized officers, staff, agents and employees, either individually or through the Defendant ResMed Corp., with whom they were in privity, breached its/their duty by negligently and carelessly designing, planning, manufacturing, assembling, equipping, testing, inspecting, distributing, marketing and selling, warning, instructing and in otherwise failing to exercise reasonable care relative to the Astral 150 Ventilator so as to cause it to be defective and unreasonably dangerous to any person or persons using it in a reasonably foreseeable manner and for the purpose for which it was intended.
- 130. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, manufactured, distributed, leased, rented, and sold a medical device which was unreasonably dangerous and defective in its normal anticipated use. In addition, the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, agents or employees, had prior notice or knowledge of the unreasonably dangerous conditions which were present in the subject product and failed to take proper and indicated steps to correct or eliminate the defect or unreasonably dangerous condition, or to sufficiently warn of this.
- 131. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, agents or employees, was aware of problems and defects pertaining to the alarm system, as well as other systems, functions and mechanisms within the

Astral 150 Ventilator product, all of which were components of this product, and failed to correct the problem(s), such that the product was not reasonably safe in normal use.

- 132. The Astral 150 Ventilator was in an unreasonably dangerous condition at the time it left the control of the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, and it was placed into the stream of commerce for use by customers.
- 133. The Astral 150 Ventilator, including its related systems and components, failed to provide reasonable warning, alerts, instructions, and other protections and safeguards for the user of the ventilator and failed to afford reasonable protection and safety for its customers while using the product in a foreseeable manner for the purposes intended, which defects were known to the defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, and which they failed to timely correct.
- 134. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, staff, agents or employees, failed to warn of the defects and unreasonable dangers of the Astral 150 Ventilator and failed to warn its customers of such defects and unreasonable dangers, including plaintiff's decedent, Philip T. Warren.
- 135. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, staff, agents or employees, either individually or through the Defendant ResMed Corp., with whom they were in privity, were negligent in failing to include this product model in a prior recall of medical equipment which it manufactured and distributed which had similar defects and which also needed to be corrected but was not.
- 136. That as a direct and proximate result of the foregoing acts and omissions constituting the negligence of the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, staff, agents or employees, on July 25, 2020,

while he was using the Astral 150 Ventilator, the plaintiff's decedent, Philip T. Warren, suffered catastrophic injuries, conscious pain and suffering, mental anguish, and fear of impending death, and the Plaintiff claims all manner of recovery which is available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).

137. That the Plaintiff demands that a judgment be entered against the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, in an amount that exceeds the jurisdictional limitations of all lower Courts which would otherwise have jurisdiction herein.

AS AND FOR A SIXTH CAUSE OF ACTION BASED UPON STRICT PRODUCTS LIABILITY AGAINST THE DEFENDANTS APRIA HEALTHCARE GROUP, INC. AND APRIA HEALTHCARE LLC, ON BEHALF OF THE ESTATE OF PHILIP T. WARREN, THE PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 138. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "137" with the same force and effect as though same were more fully set forth at length herein.
- Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the Astral 150 Ventilator and the components/accessories used with the ventilator, which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous, or untoward adverse side effects.
- 140. At all times relevant to this action, Defendants knew or reasonably should have known that the Astral 150 Ventilator as designed was unreasonably dangerous, defective, and posed a substantial likelihood of harm when used as directed, including but not limited to the following particulars:

- a. The internal battery was malfunctioning and had to be replaced since the risk of death in ventilator-dependent patients upon such failure was so high when it was feasible to design the Astral 150 Ventilator with an emergency backup battery to prevent insufficient ventilation;
- b. The internal battery malfunction would cause multiple electronic disruptions in function and service of the Astral 150 Ventilator which negatively impacted the efficacy of the flow sensor, oxygen sensor, pressure sensor, and/or alarm system when it was feasible to design, assess, and designate the internal battery problem of the Astral 150 Ventilator as a high-level alarm instead of designating it as a low-level alarm;
- c. The internal battery of the Astral 150 ventilator had inadequate capacity which caused alarm failure due to insufficient electricity in the system when it was feasible to design the Astral 150 Ventilator with an emergency backup battery to prevent insufficient ventilation or to design it with sufficient battery capacity to safeguard against alarm failures due to insufficient electricity in the system so as to prevent false alarms, inaccurate alarms, false positive alarms, false negative alarms, and software problems;
- d. The battery malfunction caused false alarms, inaccurate alarms, false positive alarms, false negative alarms, and/or software problems when it was feasible to design the Astral 150 Ventilator with an emergency backup battery to prevent insufficient ventilation;
- e. The super capacitor would leak and damage the ventilator's electronic system and cause ventilator malfunction when it was feasible to design the Astral 150 Ventilator with an alarm system to alert the user to leakage from the super capacitor;
- f. The humidifier connected to the briefing loop permitted condensation on the oxygen flow sensor, pressure sensor, and/or oxygen saturation sensor which would cause false or inaccurate sensor readings and result in insufficient ventilation when it was feasible to design the Astral 150 Ventilator to alarm or alert the user to excess humidity/moisture;
- g. Failing to configure the alarm threshold properly so as to alert the user to any power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, wrong or low oxygen levels, and/or power disconnections when it was feasible to configure or set the alarm threshold of the Astral 150 Ventilator at an appropriate and/or increased sensitivity to detect such issues; and
- h. Designing and configurating the ventilator to keep operating notwithstanding a leak between the ventilator and the user without alarming when it was feasible to design the Astral 150 Ventilator and configure the sensors' sensitivity to alarm or alert the user to leaks in oxygen/air flow/pressure.
- 141. The design defects alleged above were a substantial contributing cause of the injuries and death suffered by Plaintiff's decedent and the damages sustained by Plaintiff. The

injuries, damages, and death suffered by Plaintiffs were the reasonably foreseeable result of Defendant ResMed and the Apria Defendants' negligence.

- 142. The Astral 150 Ventilator was defectively designed as a reasonable person who knew or should have known of the product's potential for causing injury and of the feasible alternative design(s) would have concluded that the ventilator should not have been marketed in that condition. That the plaintiff could not and would not have discovered the defect through the exercise of ordinary care.
- 143. Had Defendant ResMed and the Apria Defendants performed those tests and studies necessary to determine that the Astral 150 Ventilator and the component parts listed above should not be used on ventilator-dependent patients before Plaintiff's decedent Philip T. Warren's physician prescribed it to him, Mr. Warren would not have suffered the injuries, damages, and death described with particularity above.
- 144. As a direct and proximate cause of Defendant ResMed and the Apria Defendants' negligence, Plaintiff suffered injuries, damages, and death and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the Astral 150 Ventilator and the accessories used with the ventilator, which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous, or untoward adverse side effects.

- 146. At all times relevant to this action, Defendant ResMed and the Apria Defendants knew or reasonably should have known that the Astral 150 Ventilator was manufactured in an unreasonably dangerous and defective fashion, and due to a mishap in the manufacturing process, improper workmanship, and/or defective materials, the ventilator posed a substantial likelihood of harm when used as directed for its intended purpose and in a reasonably foreseeable manner, including but not limited to the following particulars:
 - a. The software of the subject ventilator was not properly calibrated, programmed, and/or set to an appropriate threshold during the manufacturing process and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which permitted low flow rate, low pressure, and/or leakage from the ventilator to occur without alerting Mr. Warren to the problem;
 - b. The pressure sensor, flow rate sensor, and/or oxygen saturation sensor of the subject ventilator was not properly calibrated, programmed, and/or set to an appropriate threshold during the manufacturing process and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which permitted low flow rate, low pressure, and/or leakage of oxygen/air from the ventilator to occur without alerting Mr. Warren to the problem;
 - c. The supercapacitor of the subject ventilator was defective and/or not properly connected, positioned, or installed during the manufacturing process and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which permitted leakage of fluid that damaged the electronics and sensors which caused malfunction;
 - d. The internal battery of the subject ventilator had insufficient capacity due to defective materials being utilized during the manufacturing process and it deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession and failed to alert Mr. Warren to the malfunction and caused false alarms, inaccurate alarms, false positive alarms, false negative alarms, and software problems;
 - e. The internal battery of the subject ventilator was faulty at the time it was installed and deviated in quality and performance standards compared to other identical products in the same manufacturing line at the time it left Defendants' control and possession which caused multiple electronic disruptions in function and service;

- 147. The manufacturing defects alleged above were a substantial contributing cause of the injuries and death suffered by Plaintiff's decedent and the damages sustained by Plaintiff. The injuries, damages, and death suffered by Plaintiffs were the reasonably foreseeable result of Defendant ResMed and the Apria Defendants' negligence.
- 148. The Astral 150 Ventilator was defectively manufactured as a reasonable person who knew or should have known of the product's potential for causing injury would have concluded that the ventilator should not have been marketed in that condition.
- 149. Had Defendant ResMed and the Apria Defendants performed those tests and studies necessary to determine that the Astral 150 Ventilator and the component parts listed above should not be used on ventilator-dependent patients before Plaintiff's decedent Philip T. Warren's physician prescribed it to him, Mr. Warren would not have suffered the injuries, damages, and death described with particularity above.
- 150. As a direct and proximate cause of Defendant ResMed and the Apria Defendants' negligence, Plaintiff suffered injuries, damages, and death and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- 151. The subject ventilator was manufactured by Defendant ResMed and rented and distributed by the Apria Defendants undertook the periodic service of the machine and its components.
- 152. On July 25, 2020, Plaintiff's decedent Philip T. Warren properly utilized the subject ventilator in a reasonably foreseeable manner and for its intended purpose.
- 153. On July 25, 2020, Plaintiff's decedent Philip T. Warren powered on the subject ventilator and initiated the ventilation program, correctly fitted the face mask circuit to his face,

and thereafter fell asleep. The use of the machine was to protect Mr. Warren during the periods of time while he was asleep.

- 154. That the Astral 150 Ventilator is allegedly designed and manufactured in such a way as to activate an audible and visual alarm to alert the user or caretaker to a condition that requires attention to ensure user safety such as power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection.
- 155. On July 25, 2020, the subject ventilator did not perform as intended. The subject ventilator failed to alarm or alert Mr. Warren or his wife of the power failures, low pressure, high pressure, Low Minute Ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, low Positive End Expiratory Pressure, flow sensor malfunction, and/or power disconnection of the subject ventilator.
- 156. On July 25, 2020, due to the negligence of the Defendants as aforesaid, and through no fault of the Plaintiff's decedent Philip T. Warren, he was caused to sustain catastrophic injuries resulting in his death due to hypercapnic respiratory failure secondary to neuromuscular diaphragmatic dysfunction in the setting of CMT 1A on July 25, 2020 as a result of the failure of the subject ventilator to perform as intended.
- 157. At all times relevant to this action, Defendant ResMed and the Apria Defendants had a duty to warn all health care providers and consumers or users of the risks, dangers, and adverse side effects of the Astral 150 Ventilator and the component parts / accessories used with the ventilator.

- 158. Prior to July 25, 2020, Plaintiff's decedent Philip T. Warren was prescribed an Astral 150 Ventilator by his physician pulmonologist, Dr. David Berlin of Weill Cornell Medicine.
- 159. Upon information and belief that prior to prescribing the Astral 150 Ventilator to Plaintiff's decedent Philip T. Warren, Dr. David Berlin was provided with the <u>Astral Series User Guide</u> (Exhibit 2) by Defendant ResMed and <u>The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use</u> (Exhibit 3) by the Apria Defendants. The warnings contained therein were inadequate and failed to instruct, advise, inform, apprise, or warn Dr. Berlin of the potential risks, complications, malfunction, and faultiness associated with the use of the Astral 150 Ventilator, including but not limited to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction.
- 160. Upon information and belief that had Dr. David Berlin received additional, different, and/or accurate instructions and warnings concerning the Astral 150 Ventilator, Dr. Berlin would not have prescribed the subject ventilator to Plaintiff's decedent.
- 161. Based on what Defendant ResMed and the Apria Defendants knew or should have known as described above, these Defendants failed to provide proper and necessary warnings to the medical community and users of the Astral 150 ventilator, and were otherwise negligent in one or more of the following particulars:
 - a. In failing to instruct or warn the medical community that the safety of the Astral 150 Ventilator was not fit for use in ventilator-dependent patients;
 - b. In failing to disclose to the medical community that the Astral 150 Ventilator may cause serious and permanent injury and could result in death;
 - c. In failing to provide to the medical community adequate instructions for the safe use of the Astral 150 Ventilator;

- d. In failing to instruct or warn the medical community that the Astral 150 Ventilator had internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction;
- e. In failing to instruct, warn, inform, or apprise Dr. David Berlin, plaintiff's decedent's pulmonologist, of the potential risks of the Astral 150 Ventilator, including but not limited to, internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction prior to his prescribing the Astral 150 ventilator to plaintiff's decedent:
- f. In failing to instruct, warn, inform, or apprise Dr. David Berlin, plaintiff's decedent's pulmonologist, through the <u>Astral Series User Guide</u> (Exhibit 2) provided by Defendant ResMed of the potential for malfunction due to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction; and
- g. In failing to instruct, warn, inform, or apprise Dr. David Berlin, plaintiff's decedent's pulmonologist, through The Patient/Caregiver Instruction— Home Ventilator: for Invasive and Non-Invasive Use (Exhibit 3) provided by the Apria Defendants of the potential for malfunction due to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction.
- h. In failing to update its warnings, in failing to recall its product, and in failing to retrofit its product as a result of experience, complaints, product malfunction, and incidents which required that the defendants make necessary updates, changes, safety modifications, and warnings in order to preserve patient safety.
- 162. Upon information and belief that as a result of Defendant ResMed and the Apria Defendants' failure to apprise Dr. David Berlin of the aforesaid risks, complications, malfunction, and faultiness of the Astral 150 Ventilator, Dr. David Berlin could not reasonably advise, warn, instruct, or inform plaintiff's decedent Philip T. Warren of the risks, dangers, and potential malfunction associated with the use of the Astral 150 Ventilator, which proximately caused plaintiff's decedent's injuries.
- 163. Upon information and belief that a reasonable person or prescribing physician who did in fact know of the subject ventilator's potential for causing injury would have concluded that the product should not have been prescribed to patients in that condition.

- 164. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, had a duty to exercise reasonable care in the design, manufacture, assembly, testing, analysis, inspection, marketing, labeling, servicing, calibrating, updating, leasing and sale of its subject Astral 150 Ventilator product.
- 165. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, were negligent and failed to exercise proper care and oversight in the manufacture, design, assembly, inspection, marketing, servicing, maintenance, calibration, updating, lease and sale of its Astral 150 Ventilator such that it placed into the stream of commerce a piece of medical equipment which was unreasonably dangerous and defective in its intended use; this includes the related components, systems, and accessories pertaining to this equipment.
- 166. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, staff, agents and employees either individually or through the Defendant ResMed Corp., with whom they were in privity, were negligent in the design and manufacture of its Astral 150 Ventilator, as well as a failure to provide adequate and reasonable warnings as to its function, which product was placed into the stream of commerce, despite the fact that it was unreasonably dangerous and defective in normal use.
- 167. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, by their duly authorized officers, staff, agents and employees, either individually or through the Defendant ResMed Corp., with whom they were in privity, failed to give adequate warnings of the dangerous and defective design and/or manufacture of the Astral 150 Ventilator and failed to recall and/or retrofit this equipment, including failing to properly calibrate the product or to

timely update its software, although they knew or reasonably should have known of the unreasonable dangers and defects associated with its use and its alarm system, as well as other systems, functions and mechanisms of the product.

- 168. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, was in privity with the defendant ResMed Corp., in the manufacture, distribution, leasing, and sale of the subject Astral 150 Ventilator and they did place this product into the stream of commerce whereupon it came to be used by the plaintiff's decedent, who was a customer of the defendants.
- 169. That on July 25, 2020, the Plaintiff's decedent suffered catastrophic injuries which led to his death arising from an incident which occurred as a direct and proximate result of the design and manufacturing defects in the Astral 150 Ventilator along with its components, accessories, and alarm system, and the failure to provide adequate and reasonable warnings, all arising from the negligence of the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, which are responsible and liable to the Plaintiff under principles of strict products liability.
- 170. That as a direct and proximate result of the negligence and strict products liability of the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, which incorporated design defects and manufacturing flaws into the Astral 150 Ventilator, as week as a failure to warn, which rendered this product unreasonably dangerous and defective in normal use, the plaintiff's decedent suffered catastrophic injuries, conscious pain and suffering, mental anguish, and fear of impending death, as the result of an incident which occurred on July 25, 2020. As a result of the foregoing, the survivors of the decedent and his Estate have sustained

all forms of monetary damages which are recoverable under common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).

171. That the Plaintiff demands that a judgment be entered against the defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, in an amount which exceeds the jurisdictional limitations of all lower Courts which would otherwise have jurisdiction herein.

AS AND FOR A SEVENTH CAUSE OF ACTION ON BEHALF OF THE ESTATE OF PHILIP T. WARREN ARISING FROM BREACH OF WARRANTY AGAINST THE DEFENDANTS APRIA HEALTHCARE GROUP, INC. AND APRIA HEALTHCARE LLC, THE PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 172. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "171" with the same force and effect as though same were more fully set forth at length herein.
- 173. The Defendant ResMed and the Apria Defendants, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, expressly warranted and represented that the Astral 150 Ventilator was fit, was reasonably safe, capable, and was of merchantable quality.
- 174. Upon information and belief that Defendant ResMed issued, provided, authored, wrote, and delivered the <u>Astral Series User Guide</u> (Exhibit 2) and the Apria Defendants issued, provided, authored, wrote, and delivered <u>The Patient/Caregiver Instruction Home Ventilator:</u> for <u>Invasive and Non-Invasive Use</u> (Exhibit 3) to the medical community and potential purchasers or renters of the Astral 150 Ventilator, and more particularly, to Plaintiff's decedent and his physician, Dr. David Berlin, who prescribed the subject ventilator to him.
- 175. Upon information and belief that Plaintiff's decedent's physician, Dr. David Berlin, received, read, and reviewed the ResMed Astral Series User Guide provided by

Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction – Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) and relied on the material statements, affirmations, promises, and express warranties stated therein prior to prescribing the Astral 150 ventilator to Plaintiff's decedent.

- 176. Upon information and belief that Plaintiff's decedent Philip T. Warren received, read, and reviewed the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) and relied on the material statements, affirmations, promises, and express warranties stated therein prior to renting and using the subject ventilator.
- 177. Upon information and belief that Plaintiff's decedent's physician pulmonologist, Dr. David Berlin, completely read and reviewed the entirety of the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) to become familiar, acquainted, and knowledgeable with the operation, use, and maintenance of the Astral 150 Ventilator prior to recommending, advising, and/or prescribing the Astral 150 Ventilator to Plaintiff's decedent.
- 178. Upon information and belief that Plaintiff's decedent Philip T. Warren completely read and reviewed the entirety of the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) to become familiar, acquainted, and knowledgeable with the operation, use, and maintenance of the Astral 150 Ventilator prior to deciding to rent and utilize the subject ventilator.

- 179. Based on what Defendant ResMed and the Apria Defendants knew or should have known as described above, these Defendants deviated from principles of due care, deviated from the standard of care, and breached one or more of the following express warranties:
 - a. ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2):
 - i. Pg. 1: "The Astral device provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation."
 - ii. Pg. 38: "An internal battery is included in the Astral device. It ensures a continuous power supply when main power is disrupted and no external battery is connected to the device."
 - iii. Pg. 42: "The Astral device activates alarms to alert you to conditions that require attention to ensure patient safety. When an alarm is activated, the Astral device provides both audible and visual alerts, and displays an alarm message in the Alarm display on the information bar. As soon as the activation condition is met, the Astral device provides both audible and visual alerts without delay."
 - iv. Pg. 44: "High priority alarms: Total power failure; Low Pressure; Obstruction / High Pressure; High Pressure; Apnea; Low MVe (minute ventilation); Low MVi (modified ventilation index); High MVi; High MVe; Low Vte (end-tidal volume); High Vte; Low Vti (Inspiratory Tidal Volume); High Vti; Low Resp rate; High Resp rate; High Leak; Ventilation stopped; Low SpO2 (oxygen saturation); High SpO2; Low FiO2 (fraction of inspired oxygen); High FiO2; NV mask blocked; Ventilation not started. Incorrect adapter; Critically low internal battery; Circuit fault; Incorrect circuit; Unexpected restart; Internal Battery inoperable. Medium priority alarms: High pressure; Low PEEP (Positive End Expiratory Pressure); High PEEP; Low pulse rate; High pulse rate; Device overheating; Pressure line disconnected; Last self-test failed; Flow sensor not calibrated; No SpO2 monitoring; No FiO2 monitoring; Low internal battery. Low priority alarms: Power disconnected; Using internal battery; Battery 1 fault; Battery 2 fault; Power fault/ No charging."
 - b. The Patient/Caregiver Instructions Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3):
 - i. Pg. 2: "Once you are transitioned from the hospital to your home, Apria will visit you on a regular basis to provide training reinforcement and routine equipment checks and maintenance."
 - ii. Pg. 7: "It is vitally important that the ventilator be checked regularly to guarantee proper function of the ventilator and to protect against accidental changes that may occur with the controls."
 - iii. Pg. 8: "Some problems may occur during home ventilation. Usually these problems are easily resolved and there is no cause for major alarm."

- iv. Pg. 8: "In the event of a malfunction, it is important to know if there is a patient issue (e.g., the patient needs suctioning, a bronchodilator treatment, etc.) or if the equipment has malfunctioned."
- v. Pg. 8: "The ventilator must also be monitored routinely for tidal volume setting, respiratory rate, system pressure and alarm function. Mechanical problems, such as punctures or kinks in the tubing, malfunction of the exhalation valve, changes in the respiratory rate, alarm failure, or the patient's condition, can result in insufficient or decreased ventilation to the patient. Routine monitoring of the ventilator and tubing can help identify potential problems before they create difficulties."
- vi. Pg. 8: "The ventilator is equipped with safety alarms. These alarms are sensitive to low and high pressures in the ventilator circuit or airway."
- 180. That Defendant ResMed and the Apria Defendants made the aforesaid material statements which amounted to express warranties.
- 181. That Plaintiff's decedent Philip T. Warren relied on the aforesaid warranties and the material statements contained therein, as well as those provided to his physician pulmonologist who prescribed the Astral 150 Ventilator, and such reliance formed the basis for a contract with Defendant ResMed and the Apria Defendants.
- statements and express warranties contained in the ResMed Astral Series User Guide provided by Defendant ResMed (Exhibit 2) and The Patient/Caregiver Instruction Home Ventilator: for Invasive and Non-Invasive Use provided by the Apria Defendants (Exhibit 3) and the information provided by his prescribing physician based on the statements contained therein and Plaintiff's decedent was induced into purchasing or renting the Astral 150 Ventilator based on the express warranties, including but not limited to, that the subject ventilator would alert the user to malfunction(s) which could endanger the user.
- 183. That Defendant ResMed and the Apria Defendants breached the express warranties outlined above and caused catastrophic injuries to plaintiff's decedent as a result of such breach.

- 184. That Plaintiff's decedent Philip T. Warren relied on the aforesaid warranties to his detriment and as a result, was caused to sustain catastrophic injuries.
- 185. The Defendant ResMed and the Apria Defendants, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, impliedly warranted and represented that the Astral 150 Ventilator was fit, was reasonably safe to use in every respect, capable, was of merchantable quality, and had been manufactured safely.
- 186. The Defendant ResMed and the Apria Defendants, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, impliedly warranted and represented that the Astral 150 Ventilator would provide both audible and visual alarms without delay to alert the user to conditions that require attention to ensure patient safety, including but not limited to, alarms that are sensitive to low and high pressures in the ventilator circuit or airway; Total Power Failure; Low Pressure; Obstruction / High Pressure; High Pressure; Apnea; Low MVe (minute ventilation); Low MVi (modified ventilation index); High MVi; High MVe; Low Vte (end-tidal volume); High Vte; Low Vti (Inspiratory Tidal Volume); High Vti; Low Resp rate; High Resp rate; High Leak; Ventilation stopped; Low SpO2 (oxygen saturation); High SpO2; Low FiO2 (fraction of inspired oxygen); High FiO2; NV mask blocked; Ventilation not started; Incorrect adapter; Critically low internal battery; Circuit fault; Incorrect circuit; Unexpected restart; Internal Battery inoperable. Medium priority alarms: High pressure; Low PEEP (Positive End Expiratory Pressure); High PEEP; Low pulse rate; High pulse rate; Device overheating; Pressure line disconnected; Last self-test failed; Flow sensor not calibrated; No SpO2

monitoring; No FiO2 monitoring; Low internal battery. Low priority alarms: Power disconnected; Using internal battery; Battery 1 fault; Battery 2 fault; Power fault/No charging.

- 187. That the Defendant ResMed and the Apria Defendants impliedly warranted said product and its components and accessories was fit for the purpose for which it was intended as outlined in detail above, however, the subject ventilator was not reasonably fit for its intended purpose and was defective.
- 188. That the plaintiff's decedent relied upon the implied warranties of Defendant ResMed and the Apria Defendants.
- 189. That Defendant ResMed and the Apria Defendants breached the aforementioned implied warranties.
- 190. That as a result of the breach of the implied warranties by Defendant ResMed and the Apria Defendants, the plaintiff's decedent was caused to sustain catastrophic injuries, including pain and suffering, mental anguish, fear of impending death, and the survivors and estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).
- 191. The Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, in connection with their business activities as aforementioned, by its duly authorized officers, staff, and employees, or through their authorized dealers and agents, either individually or through the Defendant ResMed Corp., with whom they were in privity, warranted and represented, expressly and impliedly, that the subject Astral 150 Ventilator was fit, was reasonably safe, capable, and was of merchantable quality.

- 192. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, either individually or through the Defendant ResMed Corp., with whom they were in privity, warranted said product and its components and accessories was fit for the purpose for which it was intended, warranted that said product and its components and accessories was reasonably safe to use in every respect and had been manufactured safely and warranted that it was good, safe, and proper to use, warranted that the said product and its components and accessories was of merchantable quality and was safe for use, and provided certain written instructions in connection with the use of the product and its components and accessories.
- 193. That the Plaintiff's decedent's Astral 150 Ventilator, including its component parts and accessories, was not of a merchantable quality, nor fit for the purpose for which it was intended and was unreasonably dangerous in normal use.
- 194. That the plaintiff's decedent relied upon the express and implied warranties that accompanied the manufacturing, distribution, maintenance, and sale of the equipment.
- 195. That the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, breached the express and implied warranties which accompanied the manufacture, distribution, maintenance, and sale of the Astral 150 Ventilator all to the damage and detriment of the decedent.
- 196. That on July 25, 2020, the Plaintiff's decedent, while using the subject product in accordance with its intended use, was caused to suffer and sustain catastrophic bodily injuries, which caused conscious pain and suffering and which led to his death.
- 197. That as a result of breach of warranty of the Defendants Apria Healthcare Group, Inc. and Apria Healthcare LLC, including express and implied warranties, the plaintiff's decedent was caused to sustain catastrophic injuries, including pain and suffering, mental

anguish, fear of impending death, and the survivors and Estate claim all manner of recovery available at common law and under EPTL § 11-3.1, 11-3.2, and 11-3.3(a).

198. That as a result of the foregoing, Plaintiff is entitled to compensatory damages in an amount that exceeds the jurisdictional limitations of all lower Courts which would otherwise have jurisdiction herein.

AS AND FOR AN EIGHTH CAUSE OF ACTION BASED UPON THE WRONGFUL DEATH OF THE DECEDENT AGAINST DEFENDANTS APRIA HEALTHCARE GROUP, INC. AND APRIA HEALTHCARE LLC, THE PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 199. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "198" with the same force and effect as though same were more fully set forth at length herein.
- 200. That as a result of the negligence, strict products liability, failure to warn and breach of warranty by the defendants APRIA HEALTHCARE GROUP, INC. AND APRIA HEALTHCARE LLC, which directly and proximately caused the occurrence of the catastrophic incident of July 25, 2020, the plaintiff's decedent, Philip T. Warren, died as a result of his catastrophic injuries on July 25, 2020.
- 201. That as a result of the death of the decedent, the survivors and Estate of the decedent have and will suffer a loss of support, loss of services, loss of parental guidance, loss of advice, and all manner of wrongful death damages as are recoverable at common law and under EPTL § 5-4.1 and § 5-4.3.
- 202. That as a result of the foregoing, Plaintiff is entitled to compensatory damages and additionally, claims entitlement to prejudgment interest from July 25, 2020, that exceeds the jurisdictional limitations of all lower courts which would otherwise have jurisdiction herein.

AS AND FOR A NINTH CAUSE OF ACTION ON BEHALF OF BROOKE WARREN FOR A DERIVATIVE CAUSE OF ACTION AND LOSS OF CONSORTIUM AGAINST DEFENDANTS RESMED CORP., APRIA HEALTHCARE GROUP, INC., AND APRIA HEALTHCARE LLC, PLAINTIFF DOES ALLEGE AS FOLLOWS:

- 203. Plaintiff repeats, reiterates and realleges each and every allegation of paragraphs "1" through "202" with the same force and effect as though same were more fully set forth at length herein.
- 204. At all relevant times, the Plaintiff Brooke Warren was married to and living together with Plaintiff's decedent Philip Warren as husband and wife.
- 205. That as a result of the aforesaid acts and omissions of the Defendants, which caused the serious injuries and death of her husband, the Plaintiff Brooke Warren has sustained damages and possesses a derivative cause of action against the Defendants, as a result of the loss of her relationship with her husband. More specifically, she has been deprived of the support, assistance, relationship, consortium, and services of her husband, and has been required to provide extraordinary services and assistance and has been responsible for various charges and associated expenses.
- 206. As a result of the negligence, strict products liability, failure to warn, and breach of warranty of the defendants as set forth above, the Plaintiff Brooke Warren has suffered loss of services and the consortium of her husband the decedent Philip T. Warren, all of which are continuing in nature.
- 207. That the Plaintiff Brooke Warren has incurred expenses as a result of the injuries to and resultant death of her husband, Plaintiff's decedent Philip T. Warren.
- 208. That as a result of the foregoing, the Plaintiff Brooke Warren has sustained all forms of damages as are compensable under common law and under EPTL § 11-3.1, 11-3.2,

and 11-3.3(a), as well as wrongful death damages under EPTL §§ 5-4.1 and 5-4.3, plus

prejudgment interest for the wrongful death damages.

That by reason of the foregoing, Plaintiff Brooke Warren is entitled to

compensatory damages and prejudgment interest in an amount(s) which exceeds the

jurisdictional limitations of all lower courts which would otherwise have jurisdiction herein.

CPLR ARTICLE 16

210. That the Defendants are not entitled to avail themselves of the limited liability

provisions of CPLR Article 16 as a result of exclusions set forth in CPLR §1602(2)(iv) and

CPLR §1602(10).

WHEREFORE, the Plaintiff does demand that a judgment be entered against the

Defendants, both jointly and separately, based upon each of the causes of action set forth

herein, as well as prejudgment interest based upon the wrongful death causes of action dating

from July 25, 2020, the costs and disbursements of this action and such other and further relief

that this court deems to be just and proper.

Dated: New York, New York

January 12, 2022

Yours, etc.,

SILVER & KELMACHTER, LLP

By: /s/ Daniel B. Rubin

DANIEL B. RUBIN

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